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UNITED STATES
HOUSE OF REPRESENTATIVES

ROSA L. DELAURO
3RD DISTRICT, CONNECTICUT

June 3, 2022

The Honorable Christi A. Grimm
Inspector General
Office of the Inspector General
Department of Health and Human Services
330 Independence Avenue, SW
Washington, DC 20201

Dear Ms. Grimm:

I write to seek your assistance in investigating the enforcement discretion process and decisions made by the Food and Drug Administration (FDA) regarding the importation of infant formula. Abbott Nutrition announced a recall of several of its powdered infant formulas on February 17, 2022 after multiple consumer complaints of infant illnesses related to *Cronobacter sakazakii* and *Salmonella Newport* infections, which ultimately led to closing their Sturgis, Michigan facility.

Due to issues of market consolidation, and Abbott owning 43% of the infant formula market in the United States, the closing of the bacteria-filled Sturgis, Michigan facility without Abbott having a contingency plan led to an infant formula shortage.

In May, the Biden Administration invoked the Defense Production Act (DPA) to increase infant formula supply in the United States and launched Operation Fly Formula to quickly import infant formula from FDA-approved facilities abroad. It is crucial that this product be coming from FDA-approved facilities abroad, as we have a safety standard process that facilities must undergo for an extensive amount of time to be given approval from the FDA.

However, on May 16, 2022, the FDA issued guidance to temporarily exercise enforcement discretion with respect to certain requirements for infant formulas that may not comply with certain statutory and regulatory requirements and is seeking information from manufacturers regarding the safety and nutritional adequacy of their products. This guidance allows manufacturers to apply for consideration for the importation of their products.

The following week, on May 24, 2022, the FDA announced exercising enforcement discretion for a Kendal Nutricare product, under their Kendamil brand. Three days later, on May 27, 2022, the FDA announced exercising enforcement discretion for the importation of certain infant formula products manufactured by Bubs Australia.

The FDA has only nine full-time staff members working on the review of these applications. Additionally, the guidance does not make it mandatory for manufacturers to submit all information outlined in the guidance. Instead, manufacturers can pick and choose what to submit from the guidance list. My concern here is that the approval process for enforcement discretion is moving quickly for having only nine full-time staff members, while the standard process for approval is more extensive and takes longer. An additional concern I have is that there is no standardized application that the FDA is making their decisions from; if manufacturers are able to pick and choose what they submit from the guidance list, then there is no uniform application being submitted.

As such, I request that you investigate whether the FDA applied this enforcement discretion to the importation of infant formula in a safe manner with established plans in place. As part of this review, I encourage your office to focus on the following central questions:

- How much formula was needed to adequately restock infant formula in the United States, and what gap was importing from non-FDA facilities filling?
- What data did they base their answer above numbers from?
- What was the FDA's justification to release enforcement discretion guidance if we were already planning to import infant formula from FDA-approved facilities?
- How many applications were submitted?
- How many applications were approved?
- How many applications were denied?
- What was the FDA's established internal review process of these applications?
- While reviewing applications, what specific guidance measures did they internally require, if any, having been submitted to inform their decision making?
- Given that manufacturers do not have to submit all information outlined in the guidance, how did they compare applications? What made one facility viewed as safer than another?
- What inspections of the facilities were completed to ensure these manufacturing facilities abroad were safe and clean?
- How did they ultimately come to the decision that these facilities were safe?

- What justification did they have on each approved facility through enforcement discretion as to how they came to their decision?

- What plan did the FDA establish to test these products for safety once imported to the United States?

- What plan did the FDA establish to monitor and trace these products once imported to the United States?

- What plan did the FDA establish to respond if an enforcement discretion infant formula product leads to sickness, hospitalizations, deaths, and outbreak?

- Once the enforcement discretion expires, what plan did the FDA establish to deal with enforcement discretion manufacturers that seek full approval to the United States market to continue importing to the United States?

Thank you for your attention to this matter and your consideration of this request. Should you have any questions regarding this inquiry, please contact Marie Gualtieri (marie.gualtieri@mail.house.gov) on my staff at (202) 225-3661.

Sincerely,

Rosa L. DeLauro

ROSA L. DeLAURO
Chair
Committee on House Appropriations